**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MARYLAND**

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| **IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION** | MDL No. 2775<br>Master Docket No. 1:17-md-2775<br><br>JUDGE CATHERINE C. BLAKE<br><br>THIS DOCUMENT RELATES TO ALL BHR TRACK CASES |

## MEMORANDUM

Now pending are several motions filed by defendant Smith & Nephew to exclude the opinion testimony of the plaintiffs' expert witnesses. These motions require the court to decide whether the proffered testimony concerns matters preempted from litigation and whether various experts are qualified to offer the challenged opinions. The matter has been fully briefed and oral argument was heard on January 27, 2021. Preliminarily, the court notes the difficulty of drawing precise lines that anticipate every iteration of an opinion that may be offered in support of a specific claim that itself is yet to be precisely defined in the context of an individual case. With that caveat, and for the reasons stated herein, the court will grant in part, reserve in part, and deny in part each of the motions.

## LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence, which "was intended to liberalize the introduction of relevant expert evidence," *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), provides that a qualified expert witness "may testify in the form of an opinion or otherwise if . . . [his or her] scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). The

expert's testimony must be "based on sufficient facts or data" and must be "the product of reliable principles and methods." Fed. R. Evid. 702(b), (c). And the expert must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(d).

It is the district judge's responsibility to make an initial determination of an expert's qualifications, *see* Fed. R. Evid. 104(a), and to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993). Relevant evidence is of course that which "helps the trier of fact to understand the evidence or determine a fact in issue." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 959 (4th Cir. 2020) (internal quotation marks omitted). Reliable expert testimony is "based on scientific, technical, or other specialized knowledge and not on belief or speculation" and derives any inferences "using scientific or other valid methods." *Id.* (internal quotation marks omitted). The Supreme Court has identified five factors that the court may consider in evaluating the reliability of an expert's reasoning or methodology: (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community. *See Daubert*, 509 U.S. at 593–94. These factors, which "may or may not be pertinent in assessing reliability," are not meant to be "definitive" or to constitute a "checklist." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150, 151 (1999) (internal quotation marks omitted).

"As in all questions of admissibility," the party seeking the admission of expert testimony "must come forward with evidence from which the court can determine that the proffered testimony is properly admissible"—i.e., that it is reliable and relevant. *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Yet the trial court's role as a gatekeeper is not

intended to serve as a "replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, 892 F.3d 624, 631 (4th Cir. 2018) (internal quotation marks omitted).

## ANALYSIS

The plaintiffs have retained as expert witnesses Larry Spears, Mari Truman, Jeffrey Shapiro, Yadin David, and L. Scott Marshall. Smith & Nephew contends that much of the testimony offered by these experts is inadmissible for either of two primary reasons: (1) it is irrelevant insofar as it only relates to claims preempted from this litigation and (2) the experts are not qualified to offer certain opinions. The court will first clarify which claims are preempted from litigation and then proceed to evaluate the admissibility of the various opinions challenged by Smith & Nephew.

### I. PREEMPTION

As this court has explained in previous decisions, the states are expressly preempted from establishing with respect to devices intended for human use any requirements which are different from or in addition to requirements imposed under the FDA's statutory framework governing premarket approval of such devices. *See, e.g., In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 743, 745 (D. Md. 2018) (hereinafter "*In re BHR*"); *see also* 21 U.S.C. § 360k. State law requirements are different from or in addition to requirements under the statute if (1) the federal government has established requirements applicable to the challenged medical device and (2) the state law requirements are different from or in addition to those requirements and relate to safety and effectiveness. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–24 (2008). Still, under *Riegel* states remain free to impose duties that

parallel, rather than add to, federal requirements. *Id*. at 330. A state law parallels federal requirements if it seeks to impose liability for conduct that also violates an FDA regulation. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017).

A state law is impliedly preempted by FDA regulations if the law exists "solely" by virtue of the federal requirements and is not a "traditional state tort law which [] predate[s] the federal enactments in question[]." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *see* 21 U.S.C. 337(a) (subject to a few enumerated exceptions, all proceedings to enforce or restrain violations of the FDA statute must be brought by the federal government). A plaintiff therefore may not transform a federal regulation into a private right of action, even if a plaintiff may rely on preexisting and traditional state tort law to assert his or her claims. *See In re BHR*, 300 F. Supp. 3d at 747.

Preemption is a significant hurdle. To survive a preemption challenge, "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink*, 860 F.3d at 1327.

This court has previously held that some of the plaintiffs' claims are preempted, including:

- any strict liability claims;
- any claim that Smith & Nephew had a duty to change its labeling;
- any claim that Smith & Nephew had a duty to directly warn patients or the medical community (as opposed to a duty to warn the FDA);
- any claim that attempts to impose liability on Smith & Nephew for claiming the BHR was safe (as opposed to safer than competitor models);
- and any claim that attempts to impose liability on Smith & Nephew for any representation the FDA required Smith & Nephew to make.

*In re BHR*, 300 F. Supp. 3d at 743, 745, 747–48. But the plaintiffs' other claims, to the extent they parallel federal obligations, are not necessarily preempted. *See id*. at 743–44.

Smith & Nephew points to this court's prior rulings to contend that much of the testimony offered by these experts is irrelevant insofar as it only relates to preempted claims. The plaintiffs' response, in essence, is that Smith & Nephew's arguments in support of preemption ignore the federal duties imposed by the conditions of the PMA approval. That approval, issued in 2006, authorized Smith & Nephew to begin commercial distribution of the BHR system subject to conditions requiring, among other things, a surgeon training program and the reporting of adverse events.

Condition No. 3 required Smith & Nephew to implement a surgeon training program "as outlined in the PMA." (ECF 2427, Ex. 9 at 6). To summarize, under Condition No. 3, the training was to include quarterly teleconferences or meetings for the first two years in order to provide clinical updates, discuss adverse events, and identify recommendations for improvements to the training program and to labeling. (*Id.*). As the plaintiffs explain in their opposition, the FDA did not initially provide any other specific requirements for the content of the surgeon training program, though Smith & Nephew created a program that was merged with the post-approval study requirements into a single document. (*See* ECF 2427, Ex. 119). The surgical training plan stated that it is important for surgeons to be "familiar with the indications, contraindications, warnings, and precautions." (*Id*. at ¶ 2.1). The program required Smith & Nephew to provide "thorough training" to a "Core Surgeon" group which would then acquire "actual device implantation experience." (*Id.*). The Core Surgeons would in turn "transfer their experience and knowledge to other interested surgeons in the US." (*Id.*). Both the introductory training for Core Surgeons and the later training for interested U.S. surgeons was to include lectures covering several topics, including "[a]nticipated PMA approved indications, contraindications, warnings, and precautions (as known at the time and reinforced after approval)." (*Id.* at ¶¶ 2.2, 2.4). And the

training was to be "linked to the Post-Approval Study conducted in the U.S." as the Core Surgeons and others trained under the program would "participate in a Post-Approval Study." (*Id.* at ¶ 2.6).

Condition No. 4 required Smith & Nephew to provide data—at first on a biannual basis and then on an annual basis—analyzing "adverse events and complaints (including MDRs) received regarding the BHR system." (ECF 2427, Ex. 9 at 6). Additionally, it required Smith & Nephew to "use this analysis to provide a justification for modifications to the training program, post-approval study, labeling, and/or device design." (*Id.*). And it provided that "[a]ny modification to the post-approval study, labeling, and/or device design will be submitted for FDA review and approval prior to implementation." (*Id.*). The PMA provided that "continued approval . . . is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of the original PMA." (*Id.* at 9). The PMA notes that the postapproval reports "shall include" an "[i]dentification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b)," as well as a bibliography and summary "of unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices" and "reports in the scientific literature concerning the device." (*Id.*). *See also* 21 C.F.R. § 814.84(b)(2)(i)–(ii) (requiring periodic reports to contain a summary and bibliography of unpublished and published reports of data from any clinical investigations or nonclinical laboratory studies involving the device).

Additionally, the PMA and 21 C.F.R. § 814.82(a)(9) requires Smith & Nephew to submit copies of written adverse reaction and device defect reports to the FDA after it receives or has knowledge about, among other things, "[a]ny adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device" and either "has not been addressed by the device's labeling" or "has been addressed by the device's labeling but is occurring with unexpected

severity or frequency." (ECF 2427, Ex. 9 at 9). And finally, the PMA and the Medical Device Reporting ("MDR") Regulation require Smith & Nephew to report to the FDA whenever they become aware of information that reasonably suggests a device marketed by the manufacturer may have caused serious injury or death or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. (*Id.* at 10). *See also* 21 C.F.R. § 803.10(c).

The PMA Approval Letter also advised Smith & Nephew that "the results of the post-approval studies, training program assessment, and adverse event analysis outlined in [Conditions] 1–4 . . . must be reflected in the labeling (via a supplement) when the post-approval study is completed, and/or at earlier timepoints, as needed." (ECF 2427, Ex. 9 at 6). Failure to comply with "any postapproval requirement constitutes a ground for withdrawal of approval of a PMA" and "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the act." (*Id.* at 7). And regarding warranties, the PMA letter stated any warranty statements "must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." (*Id.* at 3).

With this background in mind, the court will address Smith & Nephew's objections in turn.

### A. Premarket Approval and Fraud-on-the-FDA

Smith & Nephew believes that several opinions offered by the plaintiffs' experts impermissibly seek to challenge the FDA's decision to grant a PMA or otherwise raise a fraud-on-the-FDA claim. These opinions include, among others, the following assertions:

1. "There were numerous pieces of information that Smith & Nephew did not provide to FDA during the PMA process." (ECF 2384-3, Ex. C, Spears Report at 6).
2. "FDA would have more likely than not delayed the approval decision" if Smith & Nephew had disclosed additional information. (*Id.* at 7).

3. "Smith & Nephew failed to provide FDA and surgeons implanting the BHR a reasonable assurance of the safety and efficacy of the BHR." (*Id.* at 4).

4. Smith & Nephew's "[a]nnual reports . . . contained misleading statements about what Smith & Nephew knew about [the BHR's] performance" (*Id.* at 21).

5. Smith & Nephew failed to disclose "data to the FDA during the PMA approval process." (ECF 2385-4, Ex. B, Truman Report at 5).

6. Smith & Nephew "failed to act as a reasonably prudent manufacturer in that it did not provide a reasonable assurance of safety and efficacy to the FDA when it used and submitted only five years of McMinn's data to seek and obtain approval." (ECF 2388-3, Ex. A, David Report at 10).

7. Smith & Nephew "failed to . . . provide the FDA with information regarding the learning curve for surgeons implanting the device." (*Id.*).

The plaintiffs believe that these opinions are admissible insofar as they point to violations of federal requirements which also could establish a state law negligence claim. Specifically, the plaintiffs argue that Smith & Nephew violated its traditional state law duty to warn surgeons when it first introduced the BHR to market and that it acted negligently in seeking BHR approval based on the problematic data provided by the inventor of the BHR. (*See* ECF 2427, Opposition at 53). The plaintiffs believe violations of these state law duties can be shown through Smith & Nephew's purported violation of 21 U.S.C. § 360e, which provides that any person "seeking premarket approval for a class III device" may file with the FDA a report which "shall" contain "[a] statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted" to the FDA "are truthful and accurate and that no material fact has been omitted in the report." 21 U.S.C. § 360e(c)(2)(A)(x).

In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court described the FDA's various mechanisms to detect and punish false statements and fraud in the context of the 510(k) process—and, by reference, in the PMA approval process. 531 U.S. at 348–49. Because "the

federal statutory scheme amply empowers the FDA to punish and deter fraud" perpetrated against the agency, the Supreme Court held that a plaintiff's state-law "fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." *Id.* at 348. The Court reasoned that fraud-on-the-FDA claims would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by [the FDA], will later be judged insufficient in state court." *Id.* at 351.

That is why, as this court has previously stated, "PMA approval is a decision left to the FDA[.]" *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, No. 17-md-1775, 2018 WL 3079699, at *2 n.4 (D. Md. June 20, 2018). If the plaintiffs were allowed to challenge the premarket approval process, courts would, contrary to Congress's desire, "have the power to declare medical devices unreasonably dangerous after the FDA had already granted device approval." *In re BHR*, 300 F. Supp. 3d at 743. It is of no avail that the plaintiffs here wish to assert not that Smith & Nephew committed fraud on the FDA, but rather that it was negligent in omitting material facts when submitting its PMA. The FDA has the power to require the submission of any additional information it deems necessary during the approval process, so a state law negligence claim which would impose further disclosure requirements than already provided for in the statute is preempted. *See* 21 U.S.C. § 360e(c)(2)(A)(xi); *cf. Buckman*, 531 U.S. at 348 (citing the parallel provision for the Section 510(k) process).

But not every allegation that a manufacturer has made misrepresentations to the FDA will constitute a preempted fraud-on-the-FDA claim. In *Hughes v. Boston Scientific Corp.*, the Fifth Circuit Court of Appeals addressed the question of whether a plaintiff's state law failure to warn claim would be preempted under *Buckman*. 631 F.3d 762, 775 (5th Cir. 2011). Hughes brought a failure to warn claim against the defendant manufacturer and attempted to base the claim on the

corporation's violation of the FDA's MDR regulations. *Id.* In *Buckman*, by contrast, the plaintiffs attempted to assert a freestanding federal cause of action based solely on a violation of the FDA's regulations without reference to any parallel state law cause of action. 531 U.S. at 352–53 ("In the present case . . . the fraud claims exist solely by virtue of the [federal] disclosure requirements."). The Fifth Circuit held that Hughes' failure to warn claim, which was based on Mississippi tort law, was "not analogous to the 'fraud-on-the-FDA' theory in *Buckman*," which was based only on a violation of federal regulations. 631 F.3d at 775. Consequently, Hughes' failure to warn claims were not preempted. *Id.* at 776.

Thus, in accord with *Buckman*, the court will exclude the challenged testimony that relates to the PMA approval process.[1] The claims to which such testimony might be relevant are expressly or impliedly preempted by federal law and such testimony would invite a jury to question the FDA's decision to grant premarket approval. On the other hand, in accord with *Hughes*, the court will not exclude any opinions that Smith & Nephew failed to make adequate disclosures in its required annual reports *after* receiving premarket approval, as those opinions may be relevant to a failure to warn claim that is not preempted. Smith & Nephew cannot defeat such failure-to-warn claims, which are based on a failure to comply with the conditions of premarket approval, simply by recharacterizing such claims as fraud-on-the-FDA claims. *See Hughes*, 631 F.3d at 775.

**B. Labeling**

[1] It is a separate issue whether any experts may properly offer opinions speculating as to hypothetical actions the FDA may or may not have taken, as Spears' second challenged opinion does—and as several other challenged opinions subsequently discussed within this memorandum do. The Fifth Circuit Court of Appeals has suggested, at least on the basis of Mississippi law, that an "entirely speculative" claim about regulatory actions the FDA may have taken is an untenable theory of causation. *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 776 n.12 (5th Cir. 2011). Yet the court does not dwell on this issue because counsel for the plaintiffs represented at oral argument that the plaintiffs would not seek to admit into evidence any such speculative testimony at trial.

Smith & Nephew believes that several opinions offered by the plaintiffs' experts impermissibly seek to challenge the adequacy of the BHR system's FDA-approved labeling. These opinions include, among others, the following assertions:

1. "Smith & Nephew was aware that females and smaller heads were not doing as well as the larger head sizes and thus it was necessary to make a label change in the [IFU]." (ECF 2384-3, Ex. C, Spears Report 12).

2. "A prudent medical device company is under a duty to . . . make product or labeling modifications when it has evidence of higher than expected failure rates." (*Id.* at 19).

3. The BHR's "labeling and IFUs inadequately addressed the incidence and severity of implant failure." (ECF 2386-3, Ex. A, Shapiro Report at 3).

4. The BHR's labeling and IFUs "failed to adequately provide physicians with information they needed to assess the propriety of using the BHR implant, or to enable them to have complete and accurate discussions with their patients about the risks, benefits and alternatives to the BHR medical device." (*Id.*).

5. Smith & Nephew failed to "use the analysis of adverse events and complaints . . . to inform surgeons of the known risks associated with the BHR through label changes." (ECF 2388-3, Ex. A, David Report at 17).

6. Smith & Nephew "was under a duty to contact the FDA to request [the] addition of updated risk information as well as updated warnings [and] precautions[.]" (ECF 2385-4, Ex. B, Truman Report at 9).

7. With additional revision rate information, the "FDA would have more likely than not caused Smith & Nephew to seek product or labeling changes at that time." (ECF 2384-3, Ex. C, Spears Report at 22)

8. "The warnings and instructions provided with BHR were deficient at all times." (ECF 2385-4, Ex. B, Truman Report at 9).

The plaintiffs believe these opinions are admissible because Smith & Nephew had a duty under PMA Condition No. 4 to analyze adverse events and provide a justification for labeling changes. But Condition No. 4 does not require Smith & Nephew to change its labeling; rather, it requires Smith & Nephew to provide the FDA with an "analysis of adverse events and complaints" which Smith & Nephew "agree[d]" to use to "provide a justification for modifications" to labeling.

(ECF 2427, Ex. 9 at 6). Significantly, though, "[a]ny modification" to labeling "will be submitted for FDA review and approval prior to implementation." (*Id.*). Thus, as this court previously held, "[a]ny claim . . . that Smith & Nephew had a duty to change its labeling . . . should be preempted as an attempt to impose requirements that add to or differ from federal regulations." *In re BHR*, 300 F. Supp. 3d at 745; *see also Hughes*, 631 F.3d at 769 (holding that the plaintiff's products liability claim challenging the adequacy of FDA-approved labeling was preempted). The court will therefore exclude the challenged testimony.

However, this ruling is not to be construed as applying wholesale to each theory underlying the plaintiffs' failure to warn claims. A claim which challenges a representation the FDA blessed in the approval process is preempted, while a claim challenging a warranty above and beyond any guarantee that was explicitly or implicitly approved by the FDA is not preempted. *See Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017). The plaintiffs may pursue their failure to warn claims, but they may not do so by challenging the sufficiency of the FDA-approved labeling.

**C. Warnings**

Smith & Nephew believes that several opinions offered by the plaintiffs' experts which suggest Smith & Nephew had a duty to warn doctors are impermissible in light of this court's prior ruling that any claims Smith & Nephew had a duty to send Dear Doctor letters or other communications to surgeons are expressly preempted. *See In re BHR*, 300 F. Supp. 3d at 745. Additionally, Smith & Nephew challenges any opinion that it had a duty to make changes to its medical training program. These opinions include, among others,[2] the following assertions:

1. "[The] FDA would not have prevented Smith & Nephew from providing [additional revision] data to surgeons through . . . Dear Doctor letters." (ECF 2384-3, Ex. C, Spears Report at 11).

[2] Smith & Nephew also appears to challenge several opinions offered by Truman which go the issue of the adequacy of warnings, though it is not always clear whether those challenges are based on preemption or on Truman's qualifications. The plaintiffs rely heavily on *In re Biomet M2a Magnum Hip Implant Products Liability Litigation* to

2. Smith & Nephew should have provided revision data "to implanting surgeons . . . by way of . . . a Dear Doctor letter or other communication." (*Id.* at 20).

3. Smith & Nephew was under a duty to "communicate in unequivocal terms to the FDA and the professional and lay communities" any newly discovered information that a product did not provide a "safe patient experience." (ECF 2388-3, Ex. A, David Report at 6–7).

4. Smith & Nephew "did not notify surgeons already using its implants about failure issues when S&N made changes to the IFUs." (ECF 2386-3, Ex. A, Shapiro Report at 3).

5. "Smith & Nephew failed to . . . make changes to the . . . medical education program." (ECF 2384-3, Ex. C, Spears Report at 19).

6. Smith & Nephew's "surgeon training and medical education program failed to warn surgeons" in its core training group about the "1,000 surgery learning curve" and "about appropriate patient selection." (ECF 2386-3, Ex. A, Shapiro Report at 35).

The plaintiffs cite to *Williams v. Smith & Nephew* for the proposition that a duty to warn under Maryland law "extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning" and for the idea that "reasonable efforts" include warning a third party "such as the FDA." 123 F. Supp. 3d 733, 742–43 (D. Md. 2015) (citation omitted). At first glance, the quoted language appears to leave open the possibility that a failure to warn claim could encompass a theory that a manufacturer had a duty to directly warn surgeons or the general public. But a closer reading of the case forecloses that possibility. In analyzing the plaintiffs' failure to warn claim in that case, the court noted that the claim was premised on specific duties imposed on the manufacturer by the PMA, including the duty to provide the FDA adverse reaction and device defect reports, as well as the duty to report to the

support their argument that Truman is qualified to offer opinions about the adequacy of Smith & Nephew's warnings. No. 3:12-MD-2391, 2017 WL 10845178, at *12–13 (N.D. Ind. Dec. 21, 2017). But *In re Biomet* dealt only with Truman's qualifications, *i.e.*, whether her opinions were reliable; it did not deal with preemption, *i.e.*, whether her testimony would be relevant to claims in the litigation. Therefore, this court's preemption ruling with respect to warnings generally will apply with equal force to any opinions about the adequacy of Smith & Nephew's warnings offered by Truman specifically.

FDA whenever the manufacturer becomes aware that their device may have caused a death or serious injury. *Id*. Thus, the plaintiffs' failure to warn claims in *Williams* were, like those in *Hughes*, "based only on [the manufacturer's] failure to comply with FDA regulations" and were therefore "not expressly preempted." *Hughes*, 631 F.3d at 769.

That is why, in *In re BHR*, this court stated that any claim that Smith & Nephew had a duty to "communicate information to patients or the medical community . . . should be preempted as an attempt to impose requirements that add to or differ from federal regulations." 300 F. Supp. 3d at 745; *see also Bass v. Stryker Corp*., 669 F.3d 501, 515 (5th Cir. 2012) (noting that where the plaintiff did not plead that the defendant failed to include FDA-approved warnings, any claim that the defendant had a duty to warn consumers was preempted under Section 360(k)). Accordingly, the court will exclude the challenged testimony relating to Dear Doctor letters and other communications to the medical community or patients, but the court also notes that testimony opining that Smith & Nephew had a duty under the PMA or another federal requirement to disclose certain information to the FDA directly could still be relevant to a parallel state law failure to warn claim (as a portion of David's opinion, cited above, does), so long as that claim can be proved based on a violation of a condition imposed by the FDA.[3]

As to the claims about Smith & Nephew's duty to make changes to the medical education program, the plaintiffs have not identified any specific federal requirement which would require such changes. As this court previously noted, PMA Condition No. 3 required that Smith & Nephew

[3] *De La Paz v. Bayer Healthcare LLC* is instructive on this point. In that case, the U.S. District Court for the Northern District of California explained that "a claim based on the failure to warn the FDA of adverse events is not preempted to the extent start tort law recognizes a parallel duty," with the caveat that "a claim based on a failure to warn physicians or patients of adverse events would be preempted." 159 F. Supp. 3d 1085, 1096–97 (N.D. Cal. 2016). To state a failure to warn claim under California law, the plaintiff would have to prove that if the defendant had properly reported the adverse events to the FDA as required under federal law, that information would have reached her doctors in time to prevent her injuries. *Id.* at 1097. Ultimately, the court held that the plaintiff had pled no facts to plausibly indicate that she or her doctor would have become aware of the adverse events that were purportedly withheld even if the defendant had timely reported them. *Id.*

implement a surgeon training program, *see In re BHR*, 300 F. Supp. 3d at 744, but no requirement to make updates to that program has been identified. (ECF 2427, Ex. 9 at 6). And PMA Condition No. 4, contrary to the plaintiffs' assertion, did not require Smith & Nephew to make changes to its medical education program; rather, it required it to analyze adverse events and provide a justification for any proposed changes to its medical education program. (*Id.*). Absent a federal violation, the court must exclude any testimony suggesting Smith & Nephew had a duty to modify its training program; such a claim would add to, or differ from, the federal requirement that Smith & Nephew merely implement a training program. *See Riegel*, 552 U.S. at 330.

**D. Withdrawal**

Smith & Nephew argues that several opinions offered by the plaintiffs' experts which suggest Smith & Nephew had a duty to withdraw its BHR system from the market earlier are impermissible in light of this court's prior ruling that only the FDA has the authority to withdraw approval from a device. *See In re BHR*, 300 F. Supp. 3d at 737 n.5. The challenged opinions include, among others, the following statements:

1. Smith & Nephew's voluntary withdrawal of smaller BHR component sizes "should have been taken much earlier." (ECF 2384-3, Ex. C, Spears Report at 19)

2. "[The] FDA would have likely opened an additional line of questioning regarding risk, and would have clearly sought . . . withdrawal from the market of the BHR in head sizes 46 mm and below." (*Id.* at 27).

3. "Smith & Nephew was obligated to contraindicate use of head sizes < 48 mm and to contraindicate use of BHR in females in 2009 and again in 2012 when it withdrew the R3." (ECF 2385-4, Ex. B, Truman Report at 8).

4. "[C]atastrophic failure[s]" associated with "metal-on-metal articulation devices" should have been "a clear red flag to discontinue use of the BHR product." (ECF 2386-3, Ex. A, Shapiro Report at 10).

5. Smith & Nephew "had a duty to stop selling BHR to [certain patients]." (ECF 2388-3, Ex. A, David Report at 35).

The plaintiffs argue that Smith & Nephew voluntarily withdrew its products based on the results of post-market surveillance required by the FDA, and that therefore this decision was required under the PMA. This is only partially correct. Smith & Nephew undoubtedly had a duty, under PMA Condition No. 4 and the federal regulations, to report adverse events to the FDA. But any claim that Smith & Nephew had a duty to withdraw its products adds to or differs from the federal requirements, which vests in the FDA the sole authority to withdraw approval. 21 U.S.C. § 360e(e)(1)(A)–(B); *see also In re BHR*, 300 F. Supp. 3d at 737 n.5 ("Only the FDA has authority to withdraw approval from a device, and it did not do so here."). Accordingly, the court will exclude the challenged statements.

**E. Duties of a Reasonable Manufacturer**

Smith & Nephew also challenges any opinions offered by the plaintiffs' experts regarding the duties of a reasonable manufacturer that are not also pinned to federal requirements. The challenged opinions include, among others, the following statements:

1. "Smith & Nephew could have and should have raised more questions [about registry data in the period between 2007 and 2009] and followed up appropriately. Smith & Nephew did not provide this analysis to the FDA as required by PMA Condition No. 4." (ECF 2384-3, Ex. C, Spears Report at 9–10).

2. Smith & Nephew failed to "act as a reasonably prudent manufacturer" in that it "elected to rely on [a] single study source that was never replicated or validated by others" and that was "limited to five years of clinical data." (ECF 2388-3, Ex. A, David Report at 8).

With respect to Spears's opinion, Smith & Nephew points to his deposition testimony to conclude that he has conceded that the duty of a reasonable manufacturer is not pinned to any federal requirement at all. (*See* ECF 2384-2, Ex. B, Spears Dep. at 142:19–143:2 (Question: "[H]ave you identified anything else outside of this document from the 2007 to 2008 time period that the company failed to provide to FDA in violation of an FDA requirement?" Answer: "The answer to that is no.")). And yet Smith & Nephew's expert, Dr. Tillman, testified that companies

have a duty under the federal regulations to report to the FDA in their annual reports any published or unpublished data, including from registries, that are known or reasonably should be known to the applicant. (*See* ECF 2427, Ex. 24, Tillman Dep. at 112:10–115:15). *See also* 21 C.F.R. § 814.84(b)(2)(i)–(ii) (requiring periodic reports to contain a summary and bibliography of unpublished and published reports of data from any clinical investigations or nonclinical laboratory studies involving the device which should reasonably be known to the manufacturer).

To the extent that any expert testimony seeks to rely exclusively on state law duties that are not pinned to federal requirements, they are irrelevant to the remaining claims in this case. But Spears' challenged opinion, to the extent it is based on a violation of a federal regulation or a condition of approval, is not preempted and the court will not exclude it. David's opinion, on the other hand, will be excluded as it does not appear to be based on any federal requirement. *See Riegel*, 552 U.S. at 330. If anything, the opinion would be relevant only to a fraud-on-the-FDA claim, which as previously explained, is preempted. *See supra*, Section I.A.

**F. Unreasonably Dangerous**

Finally, Smith & Nephew challenges certain opinion testimony which seeks to establish that the BHR system was unreasonably dangerous, arguing that such testimony runs afoul of this court's prior holding that once a device obtains premarket approval a state law cannot declare it unreasonably dangerous. *See In re BHR*, 300 F. Supp. 3d at 743. The challenged opinions include:

1. "[A metal on metal system] is inherently and unreasonably dangerous and defective." (ECF 2385-4, Ex. B, Truman Report at 15).

2. "[M]etal-on-metal articulations have been shown, in general, and including the BHR device, to be at a higher risk for failure, when compared to the standard metal-on-plastic designs." (ECF 2386-3, Ex. A, Shapiro Report at 2).

3. Smith & Nephew "had a duty to . . . change the design to reduce risks to women and men [posed by implanting certain head sizes]."[4] (ECF 2388-3, Ex. A, David Report at 35).

The plaintiffs argue that this testimony supports a failure to warn theory in that Smith & Nephew was "required to provide surgeons a reasonable assurance of safety and efficacy of the BHR." (ECF 2427 at 53). Yet as this court has previously stated, Congress has left questions about the safety and efficacy of a device to the FDA. *See In re BHR*, 300 F. Supp. 3d at 743. Because premarket approval "is FDA recognition of a particular medical device's fitness for the market," once that approval is received, "the BHR system cannot be labeled unreasonably dangerous by state law[.]" *Id.* Accordingly, the court will exclude any testimony that seeks to label the BHR system inherently and unreasonably dangerous in a manner that would add to or differ from federal requirements.

## II. OTHER CHALLENGES

Smith & Nephew next raises several other challenges to the plaintiffs' expert testimony. These challenges can be grouped into the following general categories with respect to Spears, Truman, Shapiro, and David: (1) expert qualifications, (2) speculative testimony, (3) factual narratives and summaries, and (4) legal conclusions. The challenges to Marshall's testimony are made largely on grounds of relevance and reliability. The court will address each category in turn before proceeding to analyze Marshall's opinions.

### A. Qualifications

Smith & Nephew argues that Spears, who worked in the FDA's Office of Compliance, is not qualified to testify as to matters that were within the purview of the Office of Device Evaluation; that Truman, a biomedical engineer, is not qualified to testify about medical or

[4] Smith & Nephew also contends that David lacks adequate data to make this conclusion. Because the court holds that this testimony is preempted, it need not reach the issue.

regulatory matters; and that Shapiro, an orthopedic surgeon, is not qualified to testify about regulatory matters. A person qualified as an expert in one field may not necessarily be qualified in another. *See Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 425 (D. Md. 2002). But the question is one of degree and abstraction, and a court must consider a proposed expert's "full range of experience and training"—not just "his professional qualifications"—in deciding whether the expert has "sufficient specialized knowledge" to assist the jurors in deciding issues in the case. *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012) (citations and quotations omitted); *see also Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) (citing *Martin v. Fleissner GMBH*, 741 F.2d 61, 64 (4th Cir. 1984) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion.")).

*i. Spears*

Spears, who spent decades at the FDA and in private practice working on compliance issues—including PMAs—is qualified as a regulatory expert to offer opinions on the regulatory process. (*See* ECF 2384-3, Ex. C, Spears Report at 2, 42–44). The plaintiffs have not, by way of comparison, summoned a podiatrist to opine on psychiatric matters. Spears's proffered opinions were formed using the same standards as those "utilized by medical device companies to meet the pre-approval and post-approval FDA requirements for medical devices[.]" (*Id.* at 2). Spears may not have the same level of experience as someone who worked directly in the device evaluation office, but the court is convinced that his experience is sufficient to assist the trier of fact. *See Belk*, 679 F.3d at 162. The particulars of his experience and training go to the weight of his testimony and may be tested by cross-examination.[5]

[5] Spears may offer his opinion within a reasonable degree of professional certainty, but not within a reasonable degree of medical certainty, as his report at times purports to do.

*ii. Truman*

Truman, who holds numerous patents for orthopedic devices, has extensive experience with the orthopedic industry, and has experience consulting with industry on labeling requirements, offers opinions about the toxicity of particles shed by the BHR system. (ECF 2385-4, Ex. C, Truman Report at 6 ("[T]here were millions more bioreactive particles that could become toxic to tissues."). Other courts have considered similar challenges to the proper scope of Truman's expert testimony. *See Bayes v. Biomet, Inc.*, No. 4:13-cv-00800-SRC, 2020 WL 5594059, at *6 (E.D. Mo. Sept. 18, 2020) (excluding Truman's medical causation opinions but permitting testimony that relied on medical records and a medical doctor's opinion); *Hardison ex rel. Hardison v. Biomet, Inc.*, No. 5:19-CV-00069-TES, 2020 WL 4334108, at *12 (M.D. Ga. July 27, 2020) (same); *Saacsk v. Privilege Underwriters Reciprocal Exch.*, No. 16-1149, 2017 WL 3867761, at *2 (E.D. La. Feb. 2, 2017) (permitting testimony about the forces present in an accident, but not about the causes of the resulting injuries); *In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig.* (hereinafter "*In re Biomet*"), No. 3:12-MD-2391, 2017 WL 10845178, at *15 (N.D. Ind. Dec. 21, 2017).[6] In *Hardison v. Biomet*, a case concerning the M2a Magnum Hip System, Truman offered opinions on medical causation, including that "the design defect contributed to [the plaintiff's] death, injuries, and need for revision surgery." 2020 WL 4334108 at *12. In that case, the court held that Truman lacked "the requisite medical background" and excluded all of her medical causation opinions, but noted that if medical experts were to establish such opinions, Truman could then rely on those opinions for her analysis. *Id.* And in *In re Biomet*, Truman offered the opinion that Biomet's metal-on-metal devices can cause "elevated metal ions with immune response complications" and "tissue necrosis." 2017 WL 10845178 at *14. There,

[6] Unpublished opinions are cited for the soundness of their reasoning and not for their precedential value.

Truman's opinion was offered in support of one of her report's central conclusions, namely "that Biomet's metal-on-metal devices are unreasonably dangerous." *Id.* The court noted that Truman admitted she was not a surgeon or a toxicologist, but asserted in her deposition testimony that "she reviewed the peer-reviewed literature to familiarize herself with the topic because experts considering the devices' design and risks should be familiar with that literature." *Id.* Nevertheless, the court held that Truman could not testify as an expert "on the clinical effects of metal ions, but she [could] permissibly rely on other experts' opinions that metal ions cause clinical effects to support her opinion that metal-on-metal devices are unreasonably dangerous." *Id.* at *15.

In this case, Truman's opinion that despite being advertised as resistant to wear, the BHR contained "millions more bioreactive particles that could become toxic to tissues" is offered in support of her conclusion that Smith & Nephew failed to act as a reasonable medical device manufacturer insofar as it failed to warn physicians of serious risks and insofar as it misbranded the device in its medical education. (*See* ECF 2385-4, Ex. B, Truman Report at 6, 82). This opinion is not, as in *Bayes* and *Hardison*, offered to establish medical causation and it will not be excluded on those grounds. Rather, the opinion goes to the plaintiffs' potentially viable failure to warn claim. In that respect, the court will follow *In re Biomet*: to the extent that Truman's opinion that the BHR system contained bioreactive particles that could become toxic to tissues is based upon the testimony of experts qualified to express that opinion, her opinion will not be excluded.

*iii. Shapiro*

Shapiro is an orthopedic surgeon with extensive training in hip and knee implants and has reviewed available scientific literature on metal-on-metal hip implants. Smith & Nephew contends his testimony that its training program was inadequate to "certify" surgeons to use the BHR in patients is unreliable because the adequacy of its training program is a regulatory question, because

he has no experience training surgeons to implant medical devices, and because he is not familiar with what the FDA required of Smith & Nephew with respect to surgeon training.[7] The plaintiffs counter that Shapiro is qualified to offer his testimony from the perspective of a surgeon and that it would be helpful to a jury in assessing the impact of Smith & Nephew's warnings and disclosures on orthopedic surgeons. Shapiro's placement of quotation marks around the word "certify" in his report leaves the court uncertain if his proffered testimony is meant to opine on whether Smith & Nephew's program met the FDA's regulatory requirements or whether it is a more colloquial way to state that the program would not be adequate to inform a surgeon under a common law standard. The section of Shapiro's report detailing his findings on Smith & Nephew's training program makes an oblique reference to "very specific" training requirements imposed by the FDA, without naming a single specific requirement. (ECF 2386-3, Ex. A, Shapiro Report at 34). But the thrust of the opinion is that the failure to provide surgeons with data on the learning curve and patient selection resulted in an inadequate and inconsistent training program. (*Id.* at 34–35). Given the somewhat uncertain basis of this opinion, the court concludes in general terms that Shapiro is not qualified to offer testimony opining on Smith & Nephew's compliance with the various FDA regulations and requirements, but he is qualified to opine on the adequacy of the training program from the perspective of an implanting surgeon to the extent, if any, that such testimony may be relevant to any of the plaintiffs' non-preempted claims.

Smith & Nephew also challenges Shapiro's testimony that his experience performing implants led him to abandon metal-on-metal technology, concluding that it is inferior to metal-on-plastic and poses an unnecessary risk. Shapiro has never implanted a BHR device and his

[7] The proffered opinion reads: "Having full knowledge of the increased complexity and importance of proper surgical technique, and being fully aware of higher failure rates for surgeons new to the implanting techniques as well as the longer learning curve for proper implantation, the training that Smith & Nephew provided was inadequate to 'certify' them to use the BHR in patients." (ECF 2386-3, Ex. A, Shapiro Report at 3).

experience is limited to performing total hip arthroplasty. But Dr. Shapiro, in his capacity as an orthopedic surgeon, has reviewed performance data for a wide variety of hip systems. There is no requirement that a doctor have specific clinical experience implanting a particular device in order to testify about it, so long as the testimony—as here—is based upon sufficient specialized knowledge stemming from, for example, review of clinical studies and other literature. *See Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 672–73 (S.D. W. Va. Oct. 27, 2014) (knowledge in the field of pathology sufficient to qualify an expert to testify about the clinical effect of a product despite the expert never having implanted the product and never having treated patients for complications resulting therefrom). Though it is not apparent to which claim this testimony would be relevant, Dr. Shapiro is qualified to offer this testimony on any point for which it is in fact relevant.

**B. Speculative Testimony**

Smith & Nephew also argues that the plaintiffs' experts may not offer testimony that speculates as to actions the FDA may or may not have taken or that speculates as to the company's state of mind. As already noted, the plaintiffs, appropriately, do not plan to offer speculative testimony about what the FDA might or might not have done if presented with different or additional information. As to the company's state of mind, while an expert may testify "about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions," a party's "knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Eghnayem*, 57 F. Supp. 3d at 670; *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 728 (S.D. W. Va. 2014) (excluding expert testimony that did nothing more than provide subjective belief or unsupported speculation); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d

164, 192 (S.D.N.Y. 2009) (conjecture as to the "knowledge, motivations, intent, state of mind, or purposes" of a defendant are "not a proper subject for expert or even lay testimony"). Accordingly, any opinions which are based on any of the experts' subjective beliefs—as opposed to his or her specialized knowledge, skill, experience, training, or education—are unreliable and should be excluded.

**C. Historical and Factual Narratives**

Smith & Nephew objects that experts may not simply provide narratives or factual summaries of evidence, such as the summary titled "BHR Early Development Background" in Appendix C of Truman's report, because such narratives are not based on specialized knowledge. (ECF 2385-4, Ex. C, Truman at 197). An expert cannot "be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence." *In re Fosamax*, 645 F. Supp. 2d at 192 (citation and quotation omitted). But a factual narrative may be admissible when in relaying it the witness relies on her expertise to explain the context in which various documents were created, to define specialized terminology appearing in the documents, or otherwise to draw inferences requiring specialized expertise. *Id.*; *see also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, 2014 WL 3557345, at *7 (N.D. Tex. July 18, 2014) ("Expert narrative testimony is entirely permissible where the documents and other information the expert is reviewing are complicated, voluminous, or involve scientific or technical data and such narrative summary would assist the trier of fact in understanding the documents.").

Truman's summary appears in the appendix to her report in a manner not obviously related to any of her conclusions or findings. It is therefore not clear how much of Truman's summary of BHR development the plaintiffs will seek to elicit at trial, nor for what purpose. Because it is difficult to determine whether such a summary will be offered solely for the purpose of

constructing a factual narrative or for some purpose that calls for an expert's specialized knowledge, the court will reserve ruling on this issue. *See DePuy Orthopaedics*, 2014 WL 3557345, at *8 (admission of speculation and narrative testimony implicates a court's discretion over the presentation of evidence at trial and should be taken up at trial).

Shapiro's historical narrative, which concludes with the assertion that modern metal-on-metal devices have failed at catastrophic rates, appears to be tied to his opinion that the BHR system was too dangerous and should have been voluntarily withdrawn. (*See* ECF 2386-3, Ex. A, Shapiro Report at 10 ("[T]hese issues should have been a clear red flag to discontinue use of the BHR.")). As discussed previously, *see supra* Sections I.D and I.F, such opinions are not admissible because they are relevant only to preempted claims. Still, to the extent that any other portion of Shapiro's historical narrative may be offered to provide helpful context for an opinion that is relevant to one of the plaintiffs' surviving claims, the testimony may be admissible. The court reserves ruling on that issue, which is more properly addressed in the context of trial. *See DePuy Orthopaedics*, 2014 WL 3557345, at *8.

As for Shapiro's testimony summarizing Smith & Nephew's internal documents, the plaintiffs contend this is admissible insofar as they are documents that an expert may rely upon in forming his opinion. Shapiro's testimony summarizing these documents appears calculated to reach the conclusion that Smith & Nephew "used post-market surveillance to analyze adverse events and complaints" such that it "knew it had a problem with the performance of the BHR"—information which, Shapiro contends, physicians using hip implants "needed to know . . . to be able to use their medical judgment in determining whether a particular implant is viable for a particular patient." (ECF 2386-3, Ex. A, Shapiro Report at 25). Shapiro is qualified to offer opinions, if relevant, about what a physician would need to know in order to make an informed

medical judgment; however, Shapiro may not offer extensive factual summaries of Smith & Nephew's internal documents—including emails, memoranda, and other communications—unless that testimony is connected to an otherwise admissible opinion. *See In re Fosamax*, 645 F. Supp. 2d at 192.

**D. Legal Conclusions**

Smith & Nephew further objects to testimony proffered by Truman and David that appear to state legal conclusions. Rule 704(a) allows the admission of expert testimony that embraces an ultimate issue to be decided by the trier of fact, explaining that "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). This is because "questions of fact that are committed to resolution by the jury are the proper subject of opinion testimony." *United States v. McIver*, 470 F.3d 550, 561 (4th Cir. 2006). But "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible," except in a case involving a specialized industry where such a conclusion may be helpful to the trier of fact. *Id.* at 562 & n.13.

*i. Truman*

Truman's conclusion that Smith & Nephew's conduct amounts to a violation of specific statutory requirements is inadmissible as stating an improper legal conclusion for which she has no expertise. *See id.* at 562; *see also Moore v. Wright Med. Tech., Inc.*, No. 1:14-cv-62, 2016 WL 1316716, at *9–10 (S.D. Ga. Mar. 31, 2016) (excluding as unhelpful to the trier of fact testimony offered by Truman that the defendant unreasonably exposed the plaintiff to hazards and that the defendant's implant system had design and warning defects which caused the premature failure of the plaintiff's implant). Even if such a conclusion were helpful to a trier of fact because, for example, the medical device industry is so specialized, Truman is not qualified to offer such legal

conclusions. Truman's opinions that Smith & Nephew "failed to comply with BHR PMA Approval Letter Requirements" and violated the "Safe Medical Devices Act in the commercial distribution of the BHR," if offered without the more specific context provided in the report, would not merely embrace the ultimate issue—they would consume it. (ECF 2385-4, Ex. B, Truman Report at 5). And even if offered with the more helpful explanation of how Smith & Nephew purportedly violated these requirements, her testimony on this issue lies outside her area of expertise. Truman's credentials ably qualify her—and she is properly offered—as a biomedical engineering expert. But she lacks the regulatory and legal expertise necessary to reliably and helpfully opine so broadly on whether Smith & Nephew conformed its conduct to the requirements of the PMA approval letter and the relevant federal statutes.

*ii. David*

Finally, Smith & Nephew contends that David is not a regulatory expert and is not qualified to offer opinions on Smith & Nephew's compliance with FDA regulations or on the standard of care. Indeed, as Smith & Nephew points out, David is a biomedical engineer with a doctorate in educational psychology and he has never worked for the FDA. David is undoubtedly qualified to offer opinions on topics within the field of biomedical engineering. But this, by itself, does not mean he is unqualified to offer opinions on regulatory matters—so long as he has the scientific, technical, or other specialized knowledge necessary to do so reliably. *See* Fed. R. Evid. 702.

This is not the first case in which David's expert testimony on this issue has been challenged. In *Stevens v. Stryker Corp*., which Smith & Nephew relies on, the court considered a similar challenge to David's testimony, namely that he is not qualified to offer opinions about FDA regulations. No. 12-cv-63-bbc, 2013 WL 4758948, at *4 (W.D. Wis. Sept. 4, 2013). In that case, David's report consisted of "nothing but a list of regulations and conclusions that defendants

violated them, along with a narrative of historical facts that does not require an expert to interpret." *Id.* Because "nothing in David's report suggests that he is a regulatory expert," the court excluded David's testimony. *Id.* Yet the court reached a different result in *Woodard v. Stryker Corp.*, No. 11-CV-36-F, 2012 WL 3475079 (D. Wyo. July 16, 2012). In that case, relating to the 510(k) process, David likewise attempted to testify about "Stryker's alleged breach of numerous federal regulations to demonstrate that Stryker failed to act like a reasonably prudent manufacturer." *Id.* at * 7. The court noted that David had experience doing risk-assessment for the particular kind of product at issue in the litigation, that David had advised the FDA about the 510(k) review process, and that David had even participated in the 510(k) process himself. *Id.* at *8–9. Consequently, the court held that David was qualified by way of his experience and did not exclude David's testimony. *Id.* at *9.

In this case, although David is a biomedical engineer, he has in that capacity "developed and implemented a medical technology assessment process" used by the Texas Medical Center and other hospital systems. (ECF 2388-3, Ex. A, David Report at 3). This process included, among other things, evaluations of "product compliance with regulatory and technical standards." (*Id.*). The court therefore cannot conclude that "*nothing* in David's report suggests that he is a regulatory expert," *Stevens*, 2013 WL 4758948, at *4 (emphasis added), for David does have some experience with regulatory compliance, even if his formal education is not in that field. Additionally, his report is not, as in *Stevens*, exclusively a list of regulations and a conclusion that Smith & Nephew violated them, even though much of his thirty-seven-page report consists of the text of a regulation followed by extensive citations to deposition testimony showing that Smith & Nephew violated the regulation. (*See* ECF 2388-3, Ex. A, David Report at 12–30). Considering "the full range of [David's] experience and training," the court is persuaded that David possesses "sufficient

specialized knowledge" to reliably opine on any aspect of the regulatory process that is informed by his experience working on regulatory issues at the Texas Medical Center. *Belk*, 679 F.3d at 162. His testimony will therefore not be excluded as unreliable.

But the court notes that relevance is a separate hurdle. As explained previously, some of David's testimony pertains only to preempted claims concerning, for example, challenges to the PMA approval process. *See supra* Section I.A. The plaintiffs have not, as of yet, clearly identified a claim to which David's testimony would be relevant, but the court cannot at this time rule out the possibility that they may be able to do so.

**E. Marshall's Testimony**

The plaintiffs have also retained L. Scott Marshall, a materials engineer, to conduct a materials failure analysis of explanted BHR hip components from five plaintiffs. Smith & Nephew challenges Marshall's opinions 11 through 15, and 17, in which he proffers testimony about the BHR system's resistance to wear and corrosion, about the effect of metal particles and ions on the human body, about Smith & Nephew's marketing practices, and about his personal experience seeking a hip implant. Smith & Nephew argues this evidence is irrelevant and unreliable. Marshall also seeks to introduce photographs of BHR devices explanted from five plaintiffs and embedded with human tissue, which Smith & Nephew argues is unduly prejudicial.

*i. Opinions 12–14 (Comparing As-Cast to Heat-Treated Chromium Alloy)*

Smith & Nephew challenges Marshall's testimony opining that the wear and corrosion resistance of as-cast chromium cobalt materials used in Smith & Nephew's BHR system is not as effective as other heat-treated cobalt chromium alloys. Though such testimony may not be relevant, for example, to certain products liability claims already dismissed from this action, it is plainly relevant to the plaintiffs' claim that Smith & Nephew misrepresented the safety of the BHR

system by claiming it was *more* effective than other available metal hip replacements on the market. (*See* ECF 124, Master Am. Compl. ¶ 467(d)). Smith & Nephew argues that this testimony suggests the BHR is "unreasonably dangerous" and therefore is relevant only to an impermissible design defect claim. But the opinion also appears relevant to whether Smith & Nephew's representations were misleading and for that purpose it may be relevant to this action.[8]

And the opinion, based upon a review of scientific literature and upon examination of the explanted devices, is the product of reliable methods. Though, as Smith & Nephew points out, Marshall concedes that there is some conflict in the literature, this goes to the weight of Marshall's testimony rather than its admissibility. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194 (4th Cir. 2001) does not mandate a different result. In that case, the relevant portion of which concerned a medical doctor's differential diagnosis, the Fourth Circuit Court of Appeals noted that a differential diagnosis which "utterly fails" to take serious account of other potential causes of illness may be "so lacking" that a district court would be justified in excluding it. *Id.* at 202. In this case, though, Marshall based his opinion on a review of scientific literature and is not tasked with offering a differential diagnosis describing the relative probabilities of various causes or outcomes. And in *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398 (S.D.N.Y. 2005), relied upon by Smith & Nephew, the court analyzed several factors in its Daubert analysis, finding that an expert's challenged testimony satisfied *none* of the standard Daubert factors. *Id.* at 423. Additionally, it analyzed as an additional factor the consideration given to contrary evidence and concluded that the expert had ignored substantial quantities of contrary evidence. *Id.* at 425. In this case,

[8] The court does not find persuasive Smith & Nephew's objection that the Master Amended Consolidated Complaint doesn't explicitly reference misrepresentations relating to as-cast and heat-treated chromium alloys. Evidence is relevant to the extent it has any tendency to make a material fact more or less likely. *See* Fed. R. Evid. 401. The complaint alleges that Smith & Nephew "misrepresented to the medical community, patients, and the FDA the safety of the BHR" in its "communications and advertising[.]" (ECF 124 ¶¶ 24, 26). Thus, evidence which would tend to make any non-preempted portion of that claim more or less likely—as Marshall's testimony does—is relevant, regardless whether the plaintiffs explicitly identified this specific misrepresentation in their complaint.

Marshall's testimony satisfies at least some of the Daubert factors, as he relies on an analysis of peer-reviewed and published scientific literature. Accordingly, the court will not exclude his expert testimony on this point.

*ii. Opinions 11 & 15 (Wear of Chromium Alloy)*

Smith & Nephew also challenges Marshall's testimony opining that as-cast cobalt chromium alloy deteriorates and that Smith & Nephew's BHR system exhibited signs of wear and corrosion. The testimony is relevant to establishing the degree to which metallic ions could be expected to accumulate in a patient following implant. Marshall is not qualified as a medical expert to testify as to the effect that various quantities of metallic ions could have on a patient, but another qualified expert could testify to that effect.

But it is a closer question whether the testimony is reliable. Smith & Nephew argues that Marshall's testimony on this point is unreliable because the analysis is subject to a high rate of error, because it departed from the relevant standard, and because his computed tomography ("CT") analysis is not a recognized method for quantifying wear. Even if the error rate is as significant as Smith & Nephew contends, *Daubert* does not establish a bright line rule with respect to error rates. More problematic is Smith & Nephew's argument that his testing deviated from the international standard ASTM F2979–14. The crux of this argument is that Marshall was unable, during his deposition, to assure counsel that he complied with each of the governing standard's requirements. (*See, e.g.*, ECF 2387-6, Ex. D, Marshall Dep. at 235:14–236:15). But this appears not to have been the result of any ignorance of or disregard for the standard, but rather because Marshall's staff conducted some of the testing for him. (*See id.*). Marshall was aware of the standard and applied it, (*see* ECF 2387-5, Ex. C, Marshall Dep. at 73:8–20), and his lack of personal knowledge regarding whether his staff ensured that, for example, the testing room was

maintained at 20 degrees Celsius for 24 hours exactly, is a proper subject for cross examination but is not a basis to conclude that the testing as a whole is the product of unreliable methods. As for the use of the CT machine, which is not specified in the governing standard, Marshall stated that he used this primarily to confirm the results of the Coordinate Measuring Machine ("CMM"), which is specified in the governing standard. (ECF 2387-6, Ex. D, Marshall Dep. at 200:5–10). Though Marshall admits that the CT is less accurate than the CMM, he states that others in his field use both machines. (*Id.* at 200:11–23). Accordingly, the court will not exclude the CT results.

Finally, Smith & Nephew objects that Marshall, who is not offered as a case-specific expert, may not extrapolate insights gleaned from his analysis of the five explanted devices to reach conclusions applicable to all cases. This argument is not well-developed in Smith & Nephew's briefing, nor is it addressed by the plaintiffs in their opposition. The court will accordingly reserve ruling on this issue.

*iii. Opinion 17 (Effect of Metallic Particles on Human Health) & Background Information on Marketing*

Marshall, an expert in materials engineering, is not qualified to offer expert testimony on medicine or marketing. *See Giddings*, 192 F. Supp. 2d at 425. However, as with Truman, the court will follow *In re Biomet*, 2017 WL 10845178, with respect to Marshall. To the extent that Marshall's testimony that the BHR system contained bioreactive particles that could have adverse consequences for human health is based upon the testimony of experts qualified to express that opinion, and is offered in connection with another opinion which he is qualified to provide, his testimony will not be excluded. As for the background statement that Smith & Nephew aggressively marketed the BHR system, the court is not persuaded that this is the product of any specialized knowledge or training; it is therefore not an appropriate subject of expert testimony,

especially testimony offered by a materials engineer with no stated expertise in advertising or marketing. It will be excluded. *See* Fed. R. Evid. 702(a).

*iv. Photographs of Explanted Devices*

The court may exclude relevant evidence if its probative value is substantially outweighed by, among other litigation evils, unfair prejudice. *See* Fed. R. Evid. 403. The photographs of the explanted BHR systems, taken only from five plaintiffs, may be relevant to general causation to the extent that Marshall, using reliable methods, is able to extrapolate information from them to draw general conclusions about wear and corrosion on the BHR system. The photographs in question show what Smith & Nephew plausibly claims is human tissue and bone attached to the explanted devices. From the court's perspective, the risk of undue prejudice posed by these images is slight, if any exists at all. Some of the photographs appear to show very little of the explanted device, however, and instead focus on the human tissue attached thereto. (*See, e.g.*, ECF 2387-3, Ex. A, Marshall Report, Enclosure 18). Such images may have very little probative value. At this point in time it is unclear which photographs, if any, the plaintiffs may seek to enter into evidence. The court therefore reserves ruling on this issue.

*v. Marshall's Personal Experience with Hip Implants*

An expert may be qualified on the basis not just of knowledge, but also of experience. *See* Fed. R. Evid. 702. Though far-ranging testimony about Marshall's personal experience seeking a hip implant is likely to be irrelevant or unhelpful, the court reserves ruling on the admissibility of any testimony implicating Marshall's personal experience. In the context of examination at trial, the court will be better able to assess the relevance and admissibility of this testimony.

## CONCLUSION

For the reasons described above, the motions to exclude will be granted in part, reserved in part, and denied in part. A separate Order follows.

3/1/2021
Date

/s/
Catherine C. Blake
United States District Judge